

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1-5 are pending in this application and stand rejected.

Claims 1-5 have been amended.

Support for the amendment to claim 1 can be found in the specification, for example, at page 4, lines 4-16 and at page 7, lines 2-23 and in original claim 1.

Support for the amendment to claim 2 can be found in the specification, for example, at page 7, lines 12-23 and in original claim 2.

Support for the amendment to claim 3 can be found in the specification, for example, at page 7, lines 6-11 and lines 16-23 and in original claim 3.

Support for the amendment to claim 4 can be found in the specification, for example, at page 8, lines 4-20 and in original claim 4.

Support for the amendment to claim 5 can be found in the specification, for example, at page 8, lines 4-20 and in original claim 5.

Therefore, no new matter has been added by this amendment.

II. REJECTION UNDER 35 U.S.C. § 112

Claims 1-5 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite for the reasons set forth on pages 2-3 of the Office Action.

The present amendment is deemed to overcome this rejection. Specifically, the claims have been amended to include a positive recitation of method steps and conclusion steps.

The term "cell infection unit" as described throughout the specification, for instance, at page 8, lines 1-5, is an art recognized term referring to an index of virus titer. Virus titer is determined by treating non-infectious Sendai virus or influenza virus with a protease (i.e., human miniplasmin), thus transforming the viruses into their respective infectious forms. Cells, such as MDCK cells, are

then exposed to the viruses, and infected cells are labeled with fluorescent-labeled antiviral antibodies. The total number of infected cells in the culture is then counted to determine a cell infecting unit, as described in the specification at page 8, lines 1-20. Thus, the specification clearly sets forth and defines the term "a cell infection unit" which is also an art recognized term.

In view of the above, the rejection of claim 1-5 under 35 U.S.C. § 112, second paragraph, is untenable and should be withdrawn.

III. REJECTION UNDER 35 U.S.C. § 103

Claims 1-5 are rejected under 35 U.S.C. § 103(a) as obvious over Kido et al., Mol. Cells, Vol. 9, No. 3, pp. 235-244 (1999). See pages 3-4.

This rejection is respectfully traversed as applied to the amended claims for the following reasons.

Kido fails to render obvious the claimed invention, because the reference lacks a suggestion to use human miniplasmin to screen for anti-influenza virus agents, and the reference fails to disclose or suggest each and every element of the claimed invention.

As recited in amended claim 1, the claimed invention relates to a method for testing a substance for anti-influenza virus activity, which comprises reacting a substance of interest with a substrate virus and human miniplasmin, and analyzing the resultant reaction products.

According to the present invention, the analysis of the reaction products specifically involves detection of cleavage of F₀ protein of Sendai virus, detection of cleavage of HA protein of influenza virus, and determination of CIU (Cell Infecting Unit) of Sendai virus or influenza virus in MDCK cells. Through such an analysis, the present invention enables screening for anti-influenza agents.

It has been hypothesized that it is "a certain trypsin-type protease" capable of cleaving after arginine and lysine that is responsible for the cleavage of F₀ protein of Sendai virus and HA protein of influenza virus, and thus the expression of infectivity. However, the trypsin-type protease that can actually bring about the infectivity in these viruses must be such that it specifically recognizes one particular arginine residue among the 25 to 50 arginine and lysine residues present in F₀ and HA

proteins, and then cuts the proteins at that site, thereby leading to the expression of infectivity. Only a few proteases, including miniplasmin, have been identified thus far that meet this requirement.

Kido is relied upon as disclosing that miniplasmin is a protease involved with infectivity of influenza and Sendai viruses. Kido mentions the ability of rat miniplasmin to cleave F₀ and HA proteins in Sendai virus and influenza virus, respectively, but Kido fails to present specific data or conditions. The Examiner indicates that Kido suggests the importance of miniplasmin to virus infectivity. However, this is not a suggestion to use human miniplasmin for screening for anti-influenza agents as claimed. In fact, Kido lacks a suggestion to use human miniplasmin to screen for anti-influenza agents. As such, one of ordinary skill in the art would not be motivated to use human miniplasmin in an assay to screen for anti-influenza agents.

Kido also fails to disclose the use of MDCK cells and a method step for determining CIU in assays for screening for anti-influenza agents.

Therefore, Kido lacks a suggestion to use human miniplasmin in the claimed method to screen for anti-influenza virus agents, and the reference also fails to teach or suggest each and every element of the claimed invention.

In view of the above, rejection of claims 1-5 under 35 U.S.C. § 103(a) is untenable and should be withdrawn.

IV. INFORMATION DISCLOSURE STATEMENT

Attached to the Office Action is a Form PTO-1449 corresponding to Applicants' IDS filed March 13, 2002. The Examiner has crossed out the Kido et al. reference (AP on the Form PTO-1449), and has noted that there is "no translation or abstract". But, the Examiner still should have initialed this reference since a copy of the International Search Report citing the reference was submitted with the IDS. Nonetheless, attached herewith is an English abstract for Kido et al., Kagaku Ryouhou no Ryouiki, Vol. 15, No. 2, pp. 42-51 (1999). Also attached is a copy of the Form PTO-1449 submitted on March 13, 2002, which originally cited this Kido reference. Kindly consider the Kido reference and return an Examiner-initialed copy of the Form PTO-1449.

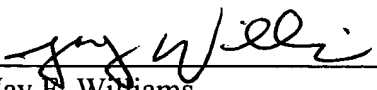
CONCLUSION

In view of the foregoing amendments and remarks, the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution in this application, the Examiner is invited to contact the undersigned attorney directly at the telephone number below.

Respectfully submitted,

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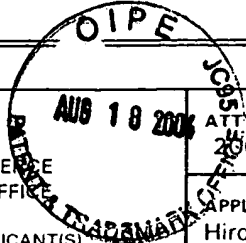
ATTACHMENTS TO AMENDMENT AND REPLY:

1. Kido Abstract (1 pg.) - Kagaku Ryouhou no Ryouiki, Vol. 15, No. 2, pp. 42-51 (1999)
2. Form PTO-1449, dated March 13, 2002

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)

Date Submitted to PTO: March 13, 2002

ATTY DOCKET NO.
2002_0319ASERIAL NO.
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Hiroshi KIDO et al.FILING DATE
March 13, 2002

GROUP

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U.S. PATENT DOCUMENTS

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OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

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| AO | Christensen, U., et al. "Enzymic Properties of the Neo-Plasmin-Val-442 (Miniplasmin)", Biochimica et Biophysica Acta, vol. 567 (1979), pages 472-481. |
| AP | Kido, H., et al. "Influenza Virus to Sendai Virus Kansen WO Seigyo suru Saibousei Protease to Protease Inhibitor", Kagaku Ryouhou no Ryouiki, vol. 15, no. 2 (1999), pages 42-51. |
| AQ | |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.